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PURPOSE

To ensure appropriate and accurate documentation and flagging is recorded in the Computerized Patient Record System (CPRS) at the Atlanta VA Health Care System (AVAHCS).

RESPONSIBILITIES

- 1) Investigators and research staff are responsible for promptly documenting each research encounter/visit with research subjects in CPRS as required.
- 2) Investigators are responsible for day-to-day supervision of their staff to ensure documentation is performed properly and accurately.

POLICY

- 1) The health records of patients participating in research studies must be flagged in CPRS by a member of the study team if determined to be required by the Atlanta VAMC Research & Development Committee (RDC).
- 2) Optional posting of a research flag is permitted as decided by the Principal Investigator.

- 3) The health record must identify the investigator, as well as contact information for a member of the research team that would be available at all times. The record must also contain information on the research study (ex. title, duration, study treatment).
- 4) The Medical Record Flag must be active for the duration of the study treatment, intervention, or clinical services that could interfere with other care.
- 5) The flag should be entered at the start of the study treatment (randomization).
- 6) The flag must be removed by a member of the study team when the patient discontinues treatment or completes their study participation.

PROCEDURE

1.0 GAIN ACCESS TO PATIENT FLAG CATEGORY II MENU

- 1) Contact the Clinical Studies Center to request access to the Patient Flag Category II menu option. A LEAF request will be submitted to AVAHCS HIM team to grant access and conduct training.

2.0 FLAGGING MEDICAL RECORDS

- 1) Sign into VISTA
- 2) Type: ^ FLAG for menu options (^ = shift and 6 key)
- 3) Type FA (FLAG ASSIGNMENT) at prompt (select item 1 or item 2)
- 4) Type "SP" to select patient
- 5) Enter the desired patient by typing the first letter of the last name and last 4 digits of the social security number. Then, hit enter. Here are some test patients that you can practice on: Z8888, Z1234, and Z7035.
- 6) Type "AF" to assign flag
- 7) At the "Select a flag for this assignment" type: Research. The computer will perform a search and Research Clinical Trial will appear, hit enter at the yes prompt.

Flag	Assigned	Review Date	Active	Local	Owner Site
1 PREGNANCY LACTATION	06/29/10	N/A	NO	YES	ATLANTA VAMC
2 MISSING PATIENT FLAG	06/29/10	N/A	NO	YES	ATLANTA VAMC

Enter ?? for more actions	
SP Select Patient	EF Edit Flag Assignment
DA Display Assignment Details	CO Change Assignment Ownership
AF Assign Flag	

Select Action: Quit / ef Assign Flag

Select a flag for this assignment: Research

Searching for a National Flag

Searching for a Local Flag

RESEARCH CLINICAL TRIAL ACTIVE CLINICAL

...OK? Yes// ☒

- 8) Press Enter at prompt "Enter Owner Site: Atlanta VAMC//".
- 9) At the prompt "Approved by", type the name of the current Chief of Staff - Dr. Robert Norvel
- 10) Then, the "Patient Record Flag-Assignment Narrative Text" box will appear
- 11) Enter the following information in the narrative text box:
 - a) Protocol Title
 - b) Name of PI and contact number
 - c) Study Coordinator and contact number
 - d) Special instructions/information
- 12) When done, press num lock and E (num lock + E saves the text) to exit narrative field.

```
Patient Record Flag - Assignment Narrative Text
==[ WRAP ]==[ INSERT ]=====< Assignment Narrative Text >====[ <PF1>H=Help ]==
This patient is currently participating in The Curious Case of Posting a
Research Flag which is an investigational study.

Please contact the Principal Investigator if additional information is
required.

Special Information:  Questions, confusion, blurred vision (side effects)
Principal Investigator:  Donndra Hall, CAC ext 2964
```

- 13) Hit enter at prompt "Enter Review Date", then hit enter again to exit.

```
Enter Review Date:  (2/23/2011 - 8/22/2011): 8/22/2011//  (AUG 22, 2011)
```

- 14) The "REVIEW OF ASSIGN FLAG DATA INPUT BEFORE FILING" screen will display. You will be asked if you would like to review this new record flag assignment. Enter "no" if you do not wish to review
- 15) Hit return/enter to "file this new record flag assignment" Please see the screen shots below

```

REVIEW OF ASSIGN FLAG DATA INPUT BEFORE FILING
-----
Patient Name: ZZGRANT,TEST
Flag Name: RESEARCH CLINICAL TRIAL
Flag Type: CLINICAL
Flag Category: II (LOCAL)
Assignment Status: ACTIVE
Initial Assignment: 2/23/2011@14:27:57
Last Review Date: N/A
Next Review Date: 8/22/2011
Owner Site: ATLANTA VAMC
Originating Site: ATLANTA VAMC
Assignment Action: NEW ASSIGNMENT
Action Date: 2/23/2011@14:30:15
Entered By: HALL,DONNDRA D
Approved By: BOWER,DAVID JAMES

Record Flag Assignment Narrative:
-----
This patient is currently participating in The
Enter RETURN to continue or '^' to exit: █

Record Flag Assignment Narrative:
-----
Research Flag which is an investigational study.

Please contact the Principal Investigator if additional information is
required.

Special Information: Questions, confusion, blurred vision (side effects)
Principal Investigator: Donndra Hall, CAC ext 2964

Action Comments:
-----
New record flag assignment.

Do you want to review again? NO//
Would you like to file this new record flag assignment? YES//
Filing the patient's new record flag assignment...
Assignment was filed successfully.
Enter RETURN to continue or '^' to exit: █

```

```

RECORD FLAG ASSIGNMENT      Feb 23, 2011@14:35:20      Page: 1 of 1
Patient: ZZGRANT,TEST (000006035)      DOB: 04/19/64
ICN: 1012707158V840906      CMOR: ATLANTA VAMC

```

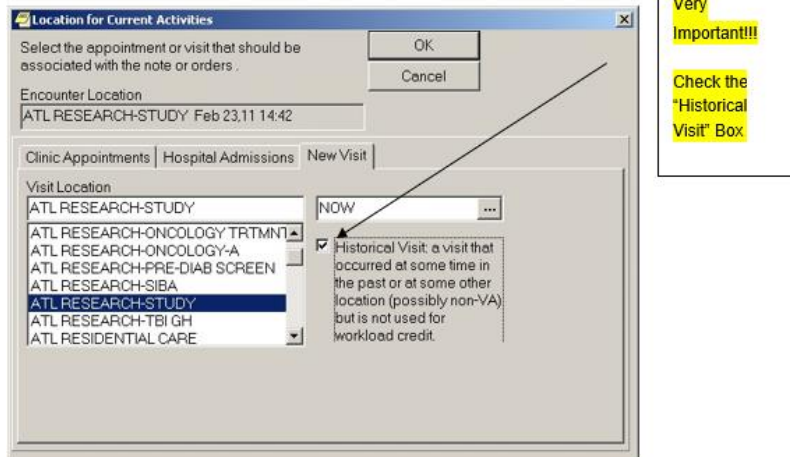
Flag	Assigned	Review Date	Active	Local	Owner Site
1 PREGNANCY LACTATION	06/29/10	N/A	NO	YES	ATLANTA VAMC
2 MISSING PATIENT FLAG	06/29/10	N/A	NO	YES	ATLANTA VAMC
3 RESEARCH CLINICAL TR	02/23/11	08/22/11	YES	YES	ATLANTA VAMC

```

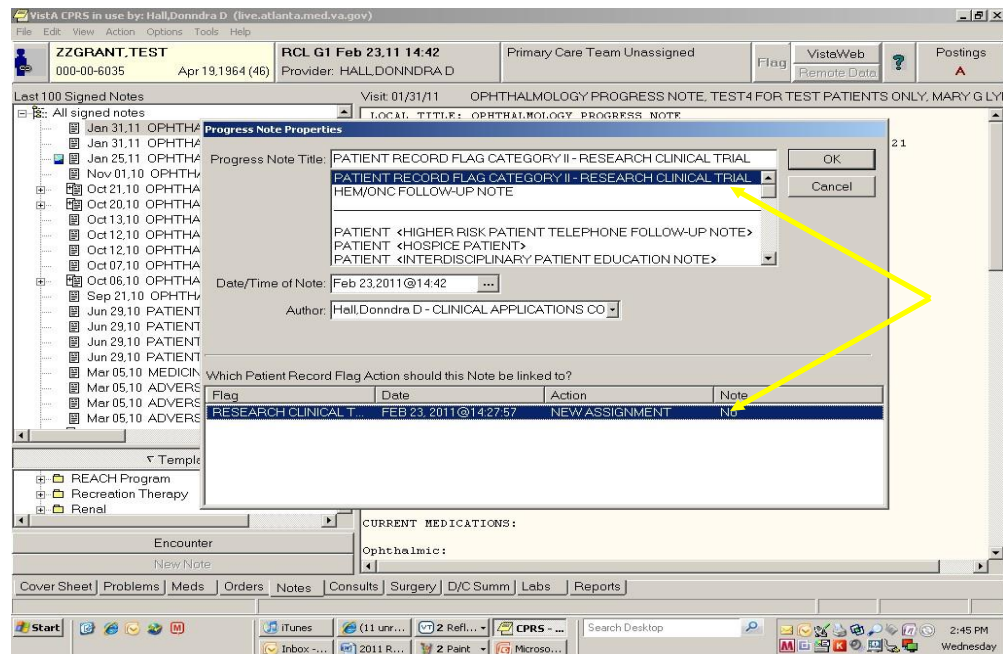
Enter ?? for more actions
SP Select Patient      EF Edit Flag Assignment
DA Display Assignment Details      CO Change Assignment Ownership
AF Assign Flag
Select Action:Quit// █

```

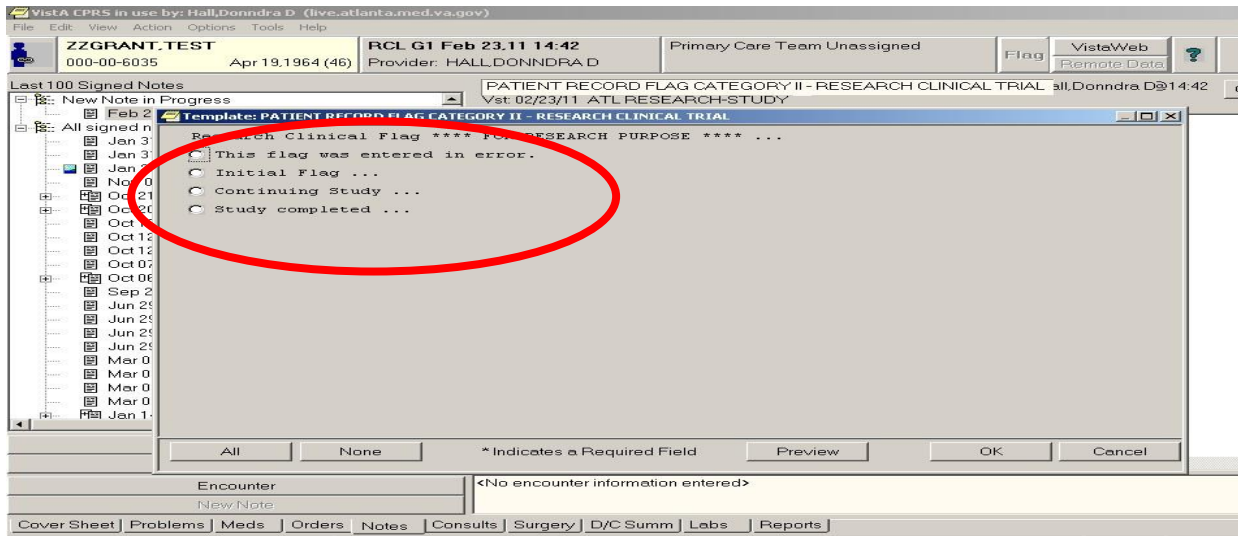
- 16) Hit return/enter to "quit" and get out of the flag menu
- 17) Go to CPRS and select desired patient. The flag should pop up on the screen. Close it and proceed to make a "New Note" in CPRS.
- 18) Select the "Notes Tab", click on "New Note", then "New Visit", and enter the "Visit Location" (e.g. "Research Study") in the box.



- 19) Enter date and time and click on the "Historical Visit Box" then "ok"
- 20) Under the progress note title, enter: "Patient Record Flag Category II-Research Clinical Trial".



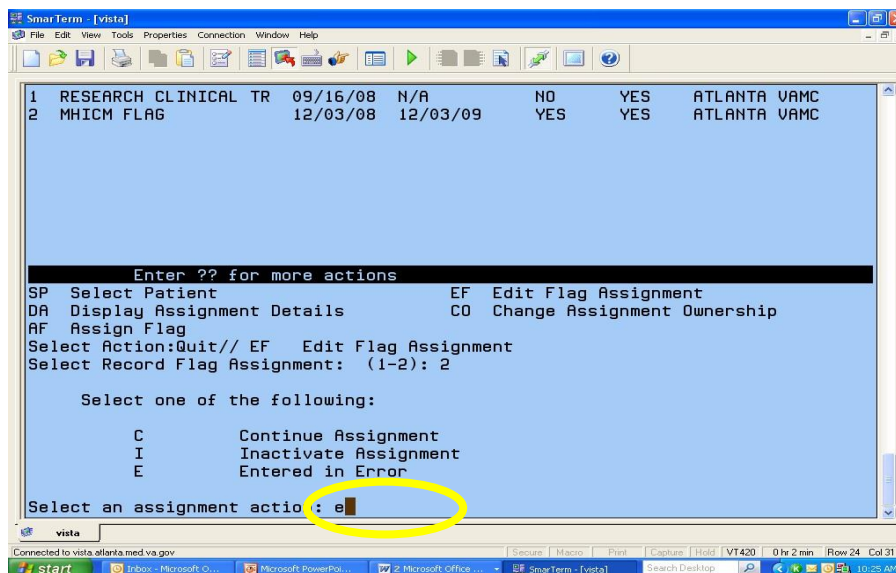
- 21) Highlight the flag shown at the bottom part (as shown in above picture) of the box and click "OK".
- 22) The note screen will appear, select the flag action, complete the template, and sign your note.



23) The flag status will be automatically reviewed every 6 months.

3.0 REMOVING OR EDITING RESEARCH FLAGS

- 1) Sign into Vista
- 2) Enter ^FLAG for menu options.
- 3) Enter FA (Flag Assignment) at prompt.
- 4) Enter SP to select patient.
- 5) Enter the first letter of the patient's last name and last 4 digits of the patient's social security number.
- 6) Enter EF (Edit Flag Assignment)
- 7) On the screen, select the number for the "Research Clinical TR" flag you would need to edit (the patient may have more than one flag).



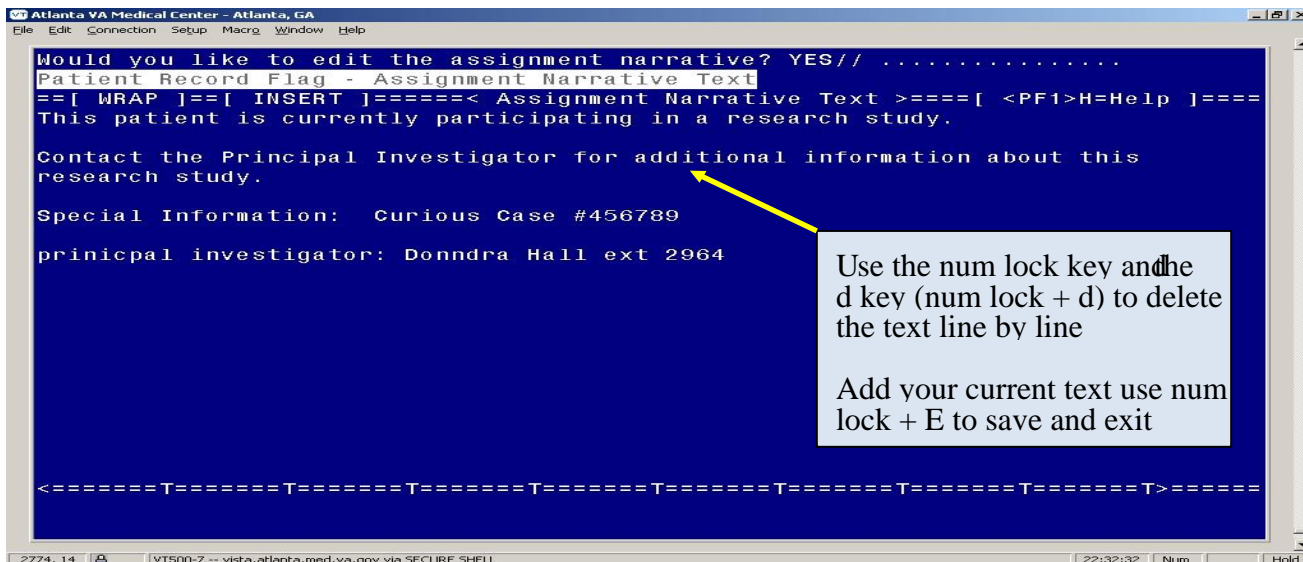
- 8) Select: "Continue Assignment" if renewing that flag, "Inactive Assignment" if discontinuing the flag" or "Entered in Error" if entered by mistake.
- 9) **If you wish to continue the flag:** You will need to hit num lock + D to delete current text and paste/copy the text you desire for "Drug Study Continues," "Investigational Device Continues" or "Clinical Intervention Continues" as appropriate or edit text as appropriate in the narrative text screen. Press "num lock + e" to save text changes and exit the narrative text box. **This is 2-step process and requires a note in CPRS as in the initial flag posting.**
- 10) **If you wish to inactivate the flag:** You will need to hit num lock + D to delete current text and paste/copy the text you desire into the "Study Completed" narrative text screen. Press "num lock + e" to save text changes and exit the narrative text box. **This is 2-step process and requires a note in CPRS as in the initial flag posting.**
- 11) **If you select Enter in error:** You will need to hit num lock + D to delete current text. Edit the flag assignment narrative to reflect the correction action taken. Press "num lock + e" to save text changes and exit the narrative text box. This is a one step process and does not require a note in CPRS.

4.0 POSTING A FLAG FOR A PATIENT THAT PREVIOUSLY PARTICIPATED IN ANOTHER RESEARCH STUDY AND NOW HAS AN "INACTIVE ASSIGNMENT"

- 1) To assign a research flag for a different study, you need log into VISTA
- 2) Type: ^FLAG for menu options
- 3) At option "Record Flag Assignment", select (FA) at the prompt
- 4) Type "SP" to select patient
- 5) Enter the desired patient by typing the first letter of the last name and last 4 digits of the social security number. Then, hit enter.
- 6) Select: "EF/ Edit Flag Assignment" as the assignment action.
- 7) Select: R Reactivate Assignment



- 8) Hit enter to “would you like to edit the assignment narrative? YES//” (as shown above)
- 9) For approved by, enter the name of the current Chief of Staff . Ask the CSC
- 10)The “Narrative Text” box with the **text previously** entered will appear on the screen



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Approved By: Correa, Ivan  CORREA,IVAN E      IEC      CHIEF OF STAFF      11
CHIEF OF STAFF
```

```
Patient Record Flag - Edit Reason Text
==[ WRAP ]==[ INSERT ]=====< Edit Reason Text >===== [ <PF1>H=Help ]=
The patient is partaking in yet another study
```

**** hit Num lock + E to save and exit

```
Enter Review Date: (2/24/2011 - 8/23/2011): 8/23/2011// (AUG 23, 2011)
```



```
REVIEW OF EDIT FLAG ASSIGNMENT DATA INPUT BEFORE FILING
-----
Patient Name: ZZBROWN,TEST
Flag Name: RESEARCH CLINICAL TRIAL
Flag Type: CLINICAL
Flag Category: II (LOCAL)
Assignment Status: ACTIVE
Initial Assignment: 6/15/2010@13:56:32
Last Review Date: 8/16/2010
Next Review Date: 8/23/2011
Owner Site: ATLANTA VAMC
Originating Site: ATLANTA VAMC
Assignment Action: REACTIVATE
Action Date: 2011/08/16 12:00:40
Entered By: HALL,DONNDRA D
Approved By: BOWER,DAVID JAMES

Record Flag Assignment Narrative:
-----
This patient is currently participating in a research study.

Enter RETURN to continue or 'Q' to exit: █

REVIEW OF EDIT FLAG ASSIGNMENT DATA INPUT BEFORE FILING
-----
Record Flag Assignment Narrative:
-----

Contact the Principal Investigator for additional information about this
research study.

Special Information: Curious Case #456789

prinicipal investigator: Donndra Hall ext 2964

Action Comments:
-----
The patient is partaking in yet another study

Do you want to review again? NO//

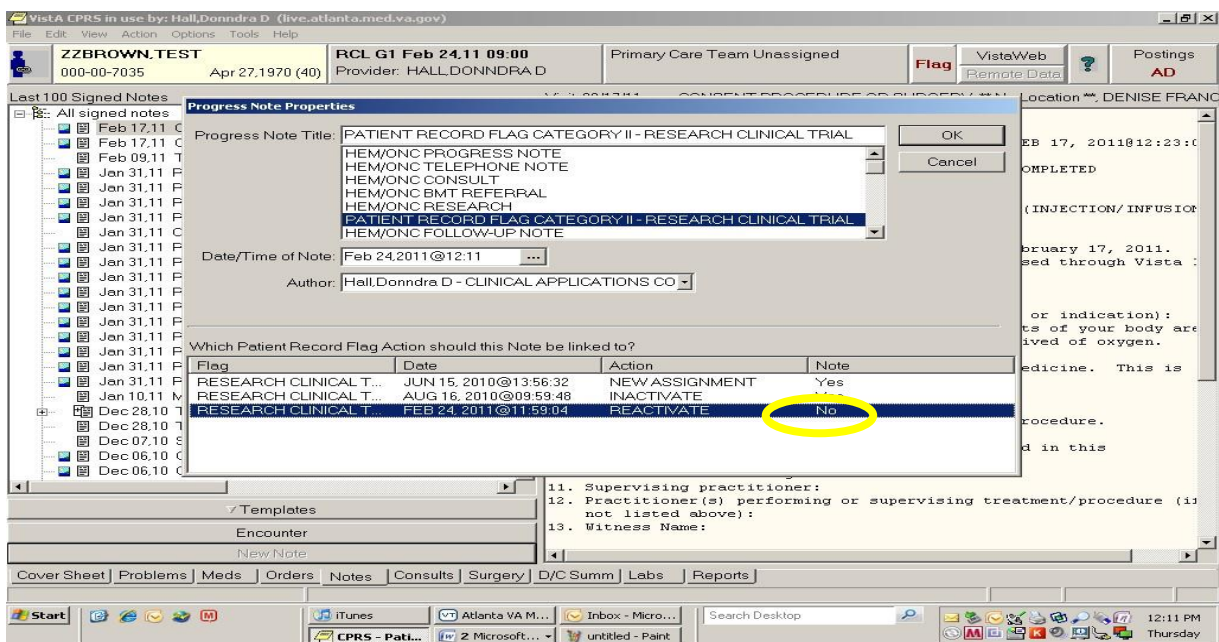
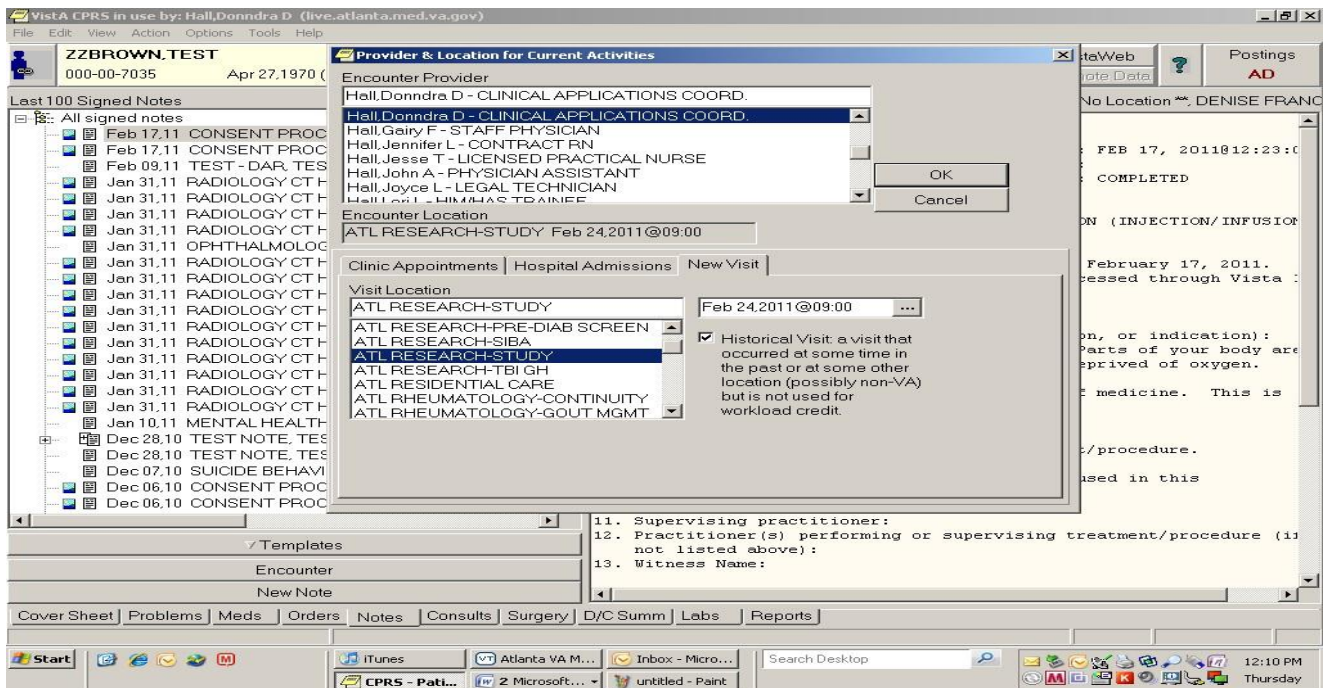
Would you like to file the assignment changes? YES//
```

- 11) You will be asked, "Do you want to review changes?" Select yes or no as appropriate.
- 12) You will be asked "Would you like to file the assignment?" Select yes. Only select no if you wish to change the information you entered.
- 13) Exit VISTA

Second Step (Not Needed For Flags "Entered In Error")

- 14) Sign into CPRS

- 15) Select patient name (Flag will NOT display if removed or inactivated). It will display if you choose to reactivate it.
- 16) Go to the "Notes" tab, click on "New Note", "New Visit", click on the historical box, enter the date and time and click "OK".
- 17) Type in "Patient Record Flag" for note title, highlight the note as shown below and click "OK".



5.0 COMMON ERROR MESSAGE

- 1) If you see this error, you must follow the instructions for Posting A Flag For A Patient That Previously Participated In Another Research Study And Now Has An “Inactivate Assignment”:

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Searching for a National Flag

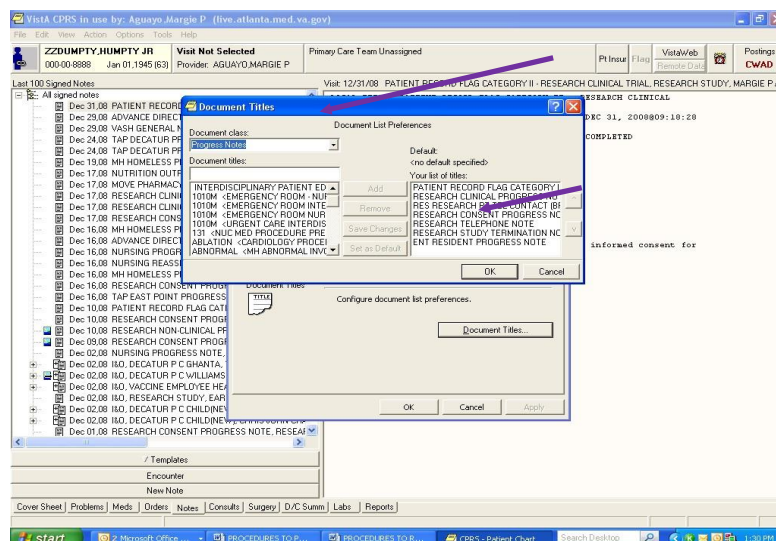
Searching for a Local Flag
RESEARCH CLINICAL TRIAL      ACTIVE      CLINICAL
...OK? Yes//      (Yes)

Unable to proceed with flag assignment...
Record flag is already assigned to patient

Enter RETURN to continue or '^' to exit: █
    
```

6.0 HOW TO SET THE “PATIENT RECORD FLAG CATEGORY II- RESEARCH CLINICAL TRIAL” NOTE AS A PREFERRED NOTE TITLE

- 1) Log into CPRS
- 2) Click on “Tools”, then “Options”.
- 3) In the Options box, select the notes tab and then the “Document Titles” box will pop up.
- 4) The document class will be “Progress Notes”. Type the “PATIENT RECORD FLAG CATEGORY II-RESEARCH CLINICAL TRIAL” to select the note in the “Document Title” section, and then click ok



- 5) To finalize, click “OK” in the “Option” box.

REFERENCES:

- 1) VHA Directive 2010-053, Patient Record Flags,
https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=2341
- 2) VHA Handbook 1907.01, Health Information Management and Health Records,
https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=9235
- 3) VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research,
https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=8171
- 4) AVAHCs Human Studies Website: <https://www.va.gov/atlanta-health-care/research/human-studies/>

REVISION HISTORY:

Revision	Date	Description of changes	Requested By
1.0	10/20/2022	Updated to new template and included new Chief of Staff	Clinical Studies Center